Comments on Fish Screening Assays and Answers to "EPA Questions for the EDMVAC"

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Comments on Fish Screening Assays in the EDSP

- USEPA should clearly define the purpose of the fish short-term reproduction test in the context of the EDSP
  - Is it a Tier 1 screen, a Tier 2 test, or in between?
- Harmonization with OECD should be enhanced to achieve global concordance in future screening results
- Fish screening assays are estrogen/androgen screens

Answers to EPA Questions on Short Term Fish Reproduction Assay

- The assay is and should be intended for the 'capture of estrogen/androgen (E/A) substances.'
  - It is neither designed nor intended for thyroid active substances.
- Previous work and the multichemical study (WA 2-29) demonstrate that the assay is capable of detecting and responding to E/A substances.
  - Not so for substances without an E/A mechanism (e.g. $CdCl_2$, perchlorate).
- The short term fish reproduction assay includes apical endpoints (fecundity and histopathology) that may be confounded by toxicity mechanisms other than E/A.
  - Although useful as potential adverse effect indicators, their inclusion in a 'screening' assay increases complexity, cost and time of the assay.
- A tiered screening approach could disaggregate the biomarker endpoints (vtg, steroids, SSC, etc.) in a first tier screen followed by apical endpoints (fecundity, histopathology) in a second tier test.
  - Substances with no effects on biomarker screening endpoints do not require apical endpoint screening/testing.